

The Examiner has rejected Claims 1-3, 9-13, 15-20 under 35 U.S.C. §103(a) as being unpatentable over Miles in view of Sullivan et al.

Miles 5,353,788 discloses a cardio-respiratory control and monitoring system for determining CPAP pressure for apnea treatment. As can be seen from Figures 1 and 2, Miles utilizes a nasal mask 3 which is coupled by a tube 2 to a CPAP device 1. Air flow pressure is measured by a pressure transducer located in the CPAP device 1. A monitor and actuating device 12 is connected to a series of sensors 5 through 11 to the device 1. The nasal mask 3 is held in place by straps surrounding the head as shown in Figure 2.

Sullivan et al. 5,522,382 discloses a device and method for treating obstructed breathing having a delay/ramp feature. Sullivan et al. uses a nose mask 12 which controls all flow into and out of the nose of the patient and is connected by electronics as shown in Figure 12 to control a motor blower for CPAP.

Claim 1 calls for a self-contained sleep monitoring apparatus. As can be readily seen, neither Miles or Sullivan et al. discloses a self-contained apparatus. Rather, extensive wiring is provided in both which is connected to remote electronics and a CPAP generator. As pointed out in the specification on page 18 with respect to applicant's apparatus, it is stated that there is provided a self-contained real-time automatic scoring apparatus so that the apparatus is ambulatory. This is certainly not true in either of the devices disclosed by Sullivan et al. or Miles in which the patient must detach himself from the other apparatus before the patient can move to another location. There certainly is no disclosure or suggestion of any such apparatus as called for in Claim 1 in either of the references cited.

Claims 2 through 16 include the subject matter of Claim 1 and are patentable for the same reason as Claim 1. They also call for additional features which are not shown by the references cited. For example Claim 2 specifies that the removable bodypiece is a headband adapted to be mounted on the head of the patient and engaging the head above the eyes and having stretchable elastic characteristics. Such a headband for carrying all of the electronics associated with the apparatus so that the apparatus can be ambulatory with the patient certainly is not shown or suggested by the references.

It should be pointed out that Sullivan et al. is collecting information for controlling CPAP, whereas the apparatus of the present invention looks at the patterns as a whole to score sleep disorders such as apnea and hypopnea. It takes more than just a plurality of sensors as taught by Miles to achieve such results. Miles utilizes a multiplicity of sensors to diagnose apnea and upon recognizing the same adjusts the CPAP pressure until the apnea is overcome.

Claim 3 calls for a respiratory disturbance index plus which is based on the sum of the event values divided by the duration of sleep of the patient. RDI stands for "Respiratory Disturbance Index" which is a well-known index that all physicians in the field refer to when they make an assessment about the severity of the disease. Applicants in accordance with the present invention have generalized the index and have added multiple sensor information to provide a more accurate representation of the disease and have identified this as RDIplus. Such apparatus certainly is not disclosed by the references cited.

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With respect to Claims 4-8, although Helmholtz resonators are known, the use of the same in the apparatus of the present invention in which a microphone is mounted in the resonator certainly is not suggested by the references, including Neumeier et al. 5,784,300. In Neumeier et al., the Helmholtz resonator is used as a damping element to increase acoustic damping and prevent excitation of unstable modes. Applicant by utilizing a microphone on the Helmholtz resonator is amplifying the properties of the Helmholtz resonator which is caused to resonate at a known frequency, i.e. 27 kilohertz, with exhaled air flow so that there is provided a proportional signal different from ambient noise or snoring sounds. Such a combination for such a purpose is not shown or suggested by the cited references.

Claims 9-16 include the subject matter of Claim 1 and are patentable for the same reason as Claim 1.

With respect to Claim 14, it calls for sensing vibrations of the trachea of the patient. Testerman et al. 5,522,862 on the other hand upon detecting obstructive sleep apnea stimulates certain muscles during an apnea event. Testerman et al. discloses an invasive device in which the phrenic nerve is stimulated. In applicants' apparatus, the sensor is mounted external of the body of the patient. It is therefore respectfully submitted that Claim 14 defines invention over the references cited.

Claim 17 is an independent method claim and calls for the use of a self-contained apparatus carried by the human being and calls for providing a real-time signal which is indicative of breathing of the patient. Such a method using a self-contained apparatus certainly is not disclosed or suggested by the references cited.

Claims 18-22 include the subject matter of Claim 17 and are patentable for the same reason as Claim 17. They also define additional steps for use with a self-contained apparatus which is not disclosed or suggested by the references cited.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue.

Formal drawings are being submitted under separate cover.

Respectfully submitted,

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